Adverse Event Reporting SIG Teleconference

Date, Time & Location:	June 18, 2004; 3:00-4:00 PM EDT; Teleconference
Attendees:	

Center	Attendee
City of Hope	Joyce Niland
City of Hope	Hemant Shah
City of Hope	Amy Cox
Mayo Clinic	Sharon Elcombe
UC Irvine	Andrea Hwang
UPMC	Doug Fridsma
Wisconsin	Rhoda Arzoomanian
Vanderbilt	Sorena nadaf
Veteran's Administration	Dave Rose
Patient Advocate	Diane Paul
NCI	Sue Dubman
NCI	Mary Jo Deering
BAH	Davis Bu
BAH	Mark Adams

Review of the AE Module Slides:

- External Requirements – Add Sponsors, SPORE Programs, DCP, DCPD, and Patients
- End Users – Add Sponsors, SPORE Programs, Clinicians, and Patients
- Interoperability with other systems that would use the AE information (e.g. Quality Improvement with the institution)

Potential Functionality of AE Module:

- All agreed with the proposed functionality with the following additions/considerations:
    - Patient Self Reporting functionality
    - Public Website
    - Automated AE Risk Detection functionality
    - Clinical Trial Identifier
    - Consider Biological Agents
    - Public Website with AE information
    - Customize Alerts:
        - SAE alerts – need to determine which SAEs need to go out immediately.
        - Identify AEs that are too soon to know and therefore an alert should not be sent out yet.
        - AEs that need to be accumulated and aggregated before any dissemination/alerts
- Need for a workflow engine to allow customizability of routing of Alerts to various stakeholders
- Need to consider caBIG architectural compliance and principles in the discussion/development of an AE System
- System needs to be modular and scalable
- Potentially use the consortium of centers working with the OnCore system as a pilot for interfaces to vendor based systems.
- Question of granularity: should it be limited to serious adverse events or all toxicities. If the system is too granular, there is the risk of losing focus, on the other hand if the scope is limited its usability will be diminished. If all toxicities are to be included, the system should also

provide for monitoring.

- Prioritization of data that needs to be collected, since the resources for data collection are limited
- API needs to be developed so that it can be utilized by other systems
- Vocabulary issues: No single vocabulary will meet the needs. Therefore there is a need to agree upon a set of standard vocabularies. There could be an umbrella vocabulary like UMLS or NCI Metathesaurus, and other more specific vocabularies used simultaneously, with the facility of creating local extensions.
- Sue Dubman mentioned that some of the newer systems have the capability of discerning emerging patterns of Adverse Events/Toxicities to provide early alerts

Next Meeting:

- First and third Fridays of every month 3:00-4:00 PM EDT (12:00-1:00 PM PDT)
- Discuss how to best structure and make the best use of time at the in person meeting on July 19 and 20

Action Items:

Name Responsible	Action Item	Date Due	Notes
Joyce Niland	COH will prepare a high level diagram regarding how centers flow the AE data including institutions with a Home grown system, institutions with a Vendor system, and institutions without a current AE system	July 19, 2004	
Joyce Niland	Make revisions/enhancements to the Dimensions diagram and the Potential Functionality of the AE Module document	July 2, 2004	

Please list below and attach Meeting Materials and Agenda (if prepared separately):